K123386

5 510(k) Summary of Safety and Effectiveness

APR 26 2013

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Tab. 1: Information regarding new device

Manufacturer name:	**Clinical House Europe GmbH**
Manufacturer address:	Opfikonerstrasse 10 8303 Bassersdorf Switzerland
Telephone number:	+49 234 974760-26
Fax number:	+49 234 974760-30
Official contact:	**Mrs Ulrike Kuckelkorn**
Date the summary was prepared:	February 5, 2013
Device trade name:	**PerioType X-Pert**
Device common name:	PerioType X-Pert
Device classification:	Implant Endosseous, root-form Product code DZE 21 CFR 872.3640 Endosseous dental implant abutment Product code NHA 21 CFR 872.3630
Establishment Registration Number	TBD
Predicate Device for the implant:	Nobel Biocare USA LLC NOBELSPEEDY IMPLANTS K050406
Predicate Device for abutment:	Nobel Estehtik Abutments K111581 Branemark System 17° angulated K944962 Branemark System Ball Attachment Abutment Syst K920452 Branemark System Titanium Healing

K123386

Abutments
K925779

Intended Use:

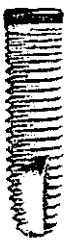
PerioType X-Pert Implants are threaded, root-form dental implants intended for use in the upper and lower jaw to support prosthetic devices, such as artificial teeth, in order to restore aesthetics and chewing function to partially or fully edentulous patients. PerioType X-Pert Dental Implant Systems are indicated for delayed loading.

The PerioType X-Pert Abutments are straight and angled dental implant Abutments to be used in conjunction with the PerioType X-Pert dental implant fixture to aid in prosthetic rehabilitation.

Device Description:

PerioType X-Pert Implants are threaded, root-form dental implants intended for use in the upper and lower jaw to support prosthetic devices, such as artificial teeth, in order to restore aesthetics and chewing function to partially or fully edentulous patients. PerioType X-Pert Dental Implant Systems are indicated for delayed loading.

The modification of the Implants are presented in the table below:



PerioType X-Pert Ø 3.5 mm (incl. Cover Screw)

XPSS3508	Ø 3.5 x 8.5 mm L
XPSS3510	Ø 3.5 x 10.0 mm L
XPSS3511	Ø 3.5 x 11.5 mm L
XPSS3513	Ø 3.5 x 13.0 mm L
XPSS3515	Ø 3.5 x 15.0 mm L
XPCSS350	Cover Screw for PerioType X-Pert Ø 3.5 mm

PerioType X-Pert Ø 4.1 mm (incl. Cover Screw)

XPS4108	Ø 4.1 x 8.5 mm L
XPS4110	Ø 4.1 x 10.0 mm L
XPS4111	Ø 4.1 x 11.5 mm L
XPS4113	Ø 4.1 x 13.0 mm L
XPS4115	Ø 4.1 x 15.0 mm L
XPCS410	Cover Screw for PerioType X-Pert Ø 4.1 mm

K123386

PerioType X-Pert Ø 5.0 mm (incl. Cover Screw)

XPS5008	Ø 5.0 x 8.5 mm L
XPS5010	Ø 5.0 x 10.0 mm L
XPS5011	Ø 5.0 x 11.5 mm L
XPS5013	Ø 5.0 x 13.0 mm L
XPS5015	Ø 5.0 x 15.0 mm L
XPCS500	Cover Screw for PerioType X-Pert Ø 5.0 mm

The Dental Implant System has an internal octagonal connection between the implant and the abutment. The surface structure of the implant is PerioCoat-R which allows for osseointegration of the implants that is substantially equivalent to the TiUnite surface from Nobel Biocare. We demonstrate the Equivalenz to the surface of the predicate device as by a direct comparative test between the device and the predicate device

Conclusion : In both cases the same coating layer was found when judged by morphological and chemical view points by the "Meyer&Horn-Salmondelkin Gbr" laboratory. They demonstrate the Equivalenz to the surface of the predicate device through a morphiolgial and chemical examination by comparison

The test demonstrate the effectiviness and safety of the device due to the Guidance AMTI 1854

We attached the report as A42

K123786

The PerioType X-Pert Abutments are straight and angled dental implant Abutments to be used in conjunction with the PerioType X-Pert dental implant fixture to aid in prosthetic rehabilitation.

ZircoSeal Abutments straight – 0° for Implants Ø 3.5 mm
(Incl. Abutment screw)

NASS390010 0° - P Ø 3.9 x 1.0 mm GH
NASS390020 0° - P Ø 3.9 x 2.0 mm GH
NASS390030 0° - P Ø 3.9 x 3.0 mm GH

ZircoSeal Abutments straight – 0° for Implants Ø 4.1 / 5.0 mm
(Incl. Abutment screw)

NAS420010 0° - P Ø 4.2 x 1.0 mm GH
NAS420020 0° - P Ø 4.2 x 2.0 mm GH
NAS420030 0° - P Ø 4.2 x 3.0 mm GH
NAS420040 0° - P Ø 4.2 x 4.0 mm GH

ZircoSeal Abutments straight – 0° for Implants Ø 4.1 / 5.0 mm
(Incl. Abutment screw)

NAS550010 0° - P Ø 5.5 x 1.0 mm GH
NAS550020 0° - P Ø 5.5 x 2.0 mm GH
NAS550030 0° - P Ø 5.5 x 3.0 mm GH
NAS550040 0° - P Ø 5.5 x 4.0 mm GH

ZircoSeal Abutments angled – 15° for Implants Ø 3.5 mm
(incl. Abutment screw)

NAAS391510 15° - P Ø 3.9 x 1.0 - 2.0 mm GH
NAAS391520 15° - P Ø 3.9 x 2.0 - 3.0 mm GH

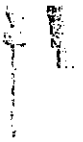
ZircoSeal Abutments angled – 15° for Implants Ø 4.1 / 5.0 mm
(incl. Abutment screw)

NAA421510 15° - P Ø 4.2 x 1.0 - 2.0 mm GH
NAA421520 15° - P Ø 4.2 x 2.0 - 3.0 mm GH
NAA421530 15° - P Ø 4.2 x 3.0 - 4.0 mm GH

ZircoSeal Abutments angled – 15° for Implants Ø 4.1 / 5.0 mm
(incl. Abutment screw)

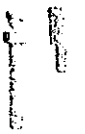
NAA551510 15° - P Ø 5.5 x 1.0 - 2.0 mm GH
NAA551520 15° - P Ø 5.5 x 2.0 - 3.0 mm GH
NAA551530 15° - P Ø 5.5 x 3.0 - 4.0 mm GH

K123386



ZircoSeal Ball Abutments for Implants Ø 3.5 mm
(without matrice)

BAS2520	2.0 mm GH - Ball Diameter 2.25 mm
BAS2540	4.0 mm GH - Ball Diameter 2.25 mm
BAS2560	6.0 mm GH - Ball Diameter 2.25 mm



ZircoSeal Ball Abutments for Implants Ø 4.1 / 5.0 mm
(without matrice)

BA2520	2.0 mm GH - Ball Diameter 2.25 mm
BA2540	4.0 mm GH - Ball Diameter 2.25 mm
BA2560	6.0 mm GH - Ball Diameter 2.25 mm

ZircoSeal Milling Cylinder for Implants Ø 4.1 / 5.0 mm
(incl. Abutment screw)

MC750	Ø 7.5 x 10.0 mm H

ZircoSeal Healing Abutments P Ø 4.5 mm for Implants Ø 3.5 mm

PHAOPS4520	Ø 4.5 x 2.0 mm GH
PHAOPS4540	Ø 4.5 x 4.0 mm GH
PHAOPS4560	Ø 4.5 x 6.0 mm GH

ZircoSeal Healing Abutments P Ø 5.2 mm for Implants Ø 4.1 / 5.0 mm

PHAOP5220	Ø 5.2 x 2.0 mm GH
PHAOP5240	Ø 5.2 x 4.0 mm GH
PHAOP5260	Ø 5.2 x 6.0 mm GH

ZircoSeal Healing Abutments P Ø 6.5 mm for Implants Ø 4.1 / 5.0 mm

PHAOP6520	Ø 6.5 x 2.0 mm GH
PHAOP6540	Ø 6.5 x 4.0 mm GH
PHAOP6560	Ø 6.5 x 6.0 mm GH

The Dental Implants and the abutments are made of Titanium Grade 4 like the Predicate Device.

The PerioType X-Pert features an implant-abutment interface with a tapered tight metal fit and an integrated platform switch. The abutments are coated with ZircoSeal™ - a hard coating layer of zirconium nitride. The implants are provided sterile, with sterility achieved by gamma radiation pursuant to ISO 11137.

Zirco Seal is the tradename of a Zirkoniumnitride coating which is used only on the abutments . ZircoSeal has been used since many years in the dentalmarket. There is no predicate device to Zirco Seal. To show the Safety and effectiviness we conducted all the testing quested by the Guidance of Modified surfaces.

Theres are attached as A29-A38 and A 45-46

K123386

K123386

Equivalence to Marketed Device:

The PerioType X-Pert is substantially equivalent to the NOBEL SPEEDY™ Implants (K050406). The candidate device and the predicate device have the same intended use, are both made of pure titanium, have similar technological characteristics, and the coatings of the implant bodies are equivalent. Both candidate and predicate device are sold in similar sizes, packed similarly, and are sterilized identically.

Summary of similaritis and modification between the devics which are subject of this 510(k) and predicate device is presented in the table below.

Element of comparison	PerioType X-Pert -new device-	NOBELSPEEDY IMPLANTS K050406 -predicate device-
		
Device description	PerioType X-Pert Implants are threaded, root-form dental implants intended for use in the upper and lower jaw to support prosthetic devices, such as artificial teeth, in order to restore aesthetics and chewing function to partially or fully edentulous patients. PerioType X-Pert Dental Implant Systems are indicated for delayed loading.	Nobel Biocare's NOBELSPEEDY™ Implants are threaded, root-form dental implants intended for use in the upper and lower jaw to support prosthetic devices, such as artificial teeth, in order to restore aesthetics and chewing function to partially or fully edentulous patients

K123386

Element of comparison	PerioType X-Pert -new device-	NOBELSPEEDY IMPLANTS K050406 -predicate device-
Indication	PerioType X-Pert Implants are threaded,root-form dental implants intended for use in the upper jaw and lower jaw to support prosthetic devices, such as artificial teeth, in order to restore aesthetics and chewing function to the patients.	NOBELSPEEDY- ™ Implants are root-form endosseous implants intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as an artificial tooth, in order to restore patient esthetics and chewing function. Nobel Biocare's NOBELSPEEDY- ™ Implants are indicated for single or multiple unit restorations in splinted or non-splinted applications. NOBELSPEEDY- ™ Implants may be placed immediately and put into immediate function providing that the initial stability requirements detailed in the surgical manuals are satisfied. NOBELSPEEDY- ™ - Implants are indicated for use in soft bone or whenever immediate or early loading is applied. The NOBELSPEEDY- ™ Implants incorporate a groove on the implant thread and are preferred over models without the groove in these soft bone indications because bone forms more rapidly in the groove than on other parts of the implant resulting in increased stability when compared to non-grooved implants. In addition, the NOBELSPEEDY-™ Implants are preferred in these soft bone indications because bone formation on the TiUnite® surface is more rapid and greater than on machined surface implants resulting in better maintenance of initial implant stability, faster and stronger osseointegration, and higher success rates. NOBELSPEEDY- ™ Implants may be tilted up to 45°. When used with angulations between 30° and 45° a minimum of four implants must be used and splinted.
Anatomical sites	Upper and lower jaw	Upper and lower jaw
design	Endosseous implant, root form, Cylinidrical shape	Endosseous Implant, root form Cylindrical shape

K123386

Element of comparison	PerioType X-Pert -new device-	NOBELSPEEDY IMPLANTS K050406 -predicate device-
Implant Prosthesis interface	Internal octagon connection	Internal hexagon connection Tri channel design
Implant neck	Micro Groove with reduced thread pitch in the crestal area of the implant	Micro Groove with reduced thread pitch in the crestal area of the implant
Thread	Self taping thread with slightly tapered apical end	Self taping thread with slightly tapered apical end
Surface:	Modified Titanium surface	Modified Titanium surface
Materials	The implants are made of pure Titanium grade 4	The Implants are made of pure Titanium grade 4
Biocompatibility:	The products comply with the ISO 7405, We state references to this in chapter 15	The products comply with the ISO 7405, We state references to this in chapter 15
Sterility:	Devices are sold gamma sterilized	Devices are sold gamma sterilized
Mechanical safety:	Endolab Fatigue test for endosseus dental implants in accordance with the ISO 14801 as reported below	Endolab Fatigue test for endosseus dental implant in accordance with the ISO 14801 as reported below

Performance Characteristics:

We conducted mechanical tests to support the substantial equivalence of the PerioType X-Pert Implant System to the Nobel Biocare Nobelspeedy Implants (K050406):

We attached the results of the Fatigue tests according to the FDA Guidance as appendix A22-A25

Conclusion: The test results shows that PerioType X Pert Implants are as Safe and effektiv as the predicate device.

K123386

K123386

As underlined by the comparison table below, the PerioType X-Pert abutments of this device can be concluded to be substantial equivalent to the predicate device:

Element of comparison	PerioTypeX-Pert ZircoSeal Abutment straight -new device-	Nobel Estehtik Abutments K111581 -predicate device-
Function:	Directly connected to the Implant and used as prosthetic device for cemented restauration for crown or bridgework.	
Height:	Availabel for diferent thickness of Gingiva: 1 mm 2 mm 3 mm and 4 mm	Availabel für diferent thickness of Gingiva: 1mm 2mm 3mm
Diameter:	ZircoSeal Abutment are produced in 3 diameters: 3,5 4,1 5.0 for the different diameters of the Implants	Nobel Estehtik Abutments are produced for 3 diameters of Implants: rp=3,3-3,5 np=4,0 wp=5,0
	The diameter of the abutment is adgusted to each Implant diameters	
Use:	singel use	singel use
Material:	titanium coated with ZircoSeal	Titanium
Biocompatibility:	Biocompatibiliy was tested to ISO 7405	
Sterility:	Devices are not sterilized	Devices are not sterilized
Conclusion:	The PerioType X-Pert abutment straight is equivalent to the predicate device because they are made from the same material and they have got the same function. The only differences is that the device is coated with Zirconiumnitrid.	

K123386

Element of comparison	ZircoSeal Abutment angulateal -new device-	Branemark System 17° angulated K944962
Function:	directly connected to the Implant and used as an prosthetic devia for cementeal restaurations for crown or bridgework	
Height:	available for 3 different Gingiva heights: 1mm-2mm 2mm-3mm 3mm-4mm	Available differant Gingiva heigts: 1mm-2mm 2mm-3mm 3mm-4mm
Diameter:	ZircoSeal Abutment are produced in 3 diameters: 3,5 4.1 5.0 for the different diameters of the Implants	Nobel Esteht\k Abutments are produced for 3 diameters of Implants: rp=3,3-3,5 np=4,0 wp=5,0
Use:	singel use	singel use
Material:	titanium coated with ZircoSeal	titanium
Biocompatibility:	Biocompatibiliy was tested to ISO 7405	
Sterility:	Devices are not sterilized	Devices are not sterilized
Conclusion:	The PerioType X-Pert Abutment angulateal is equivalent to the predicate device because they are made from the same material and they have got the same function. The only differences is that the device is coated with Zirconiumnitrid.	

K123386

Element of comparison	Periotype Ballatachment -new device-	Branemark System Ball Attachment Abutment Syst K920452
Function:	The device is an aid for the fixation of removable prosthecis	The device is an aid for the fixation of removable prosthecis
Heigt:	The device is produced for different heigt of Gingiva 2mm 4mm 6mm	The device is produced for different heigt of Gingiva 1mm 3mm 5mm
Diameter:	Diameter: 3,5 4,1 5,0	Diameter: 3,5 4,1 5,0
Use:	single use	singel use
Biocompatibility:	Biocompatibiliy was tested to ISO 7405	
Sterility:	Devices are not sterilized	Devices are not sterilized
Material:	titanium coated with ZircoSeal	titanium
Conclusion:	The PerioType X-Pert Ballattachment abutment is equivalent to the predicate device because they are made from the same material and they have got the same function. The only differences is that the device is coated with Zirconiumnitrid.	

K123386

Element of comparison	PerioType Healing Abutment -new device-	Branemark System Titanium Healing Abutments K925779
	are an surgigal aid for the healing of the gingiva when placing implants submerged or semi submerged	
	Diameter: 4,5 for 3,5mm Implants 5,2 for 4,1 and 5,0 mm Implants 6,5 for 4,1 and 5,0 mm Implants	Diameter: 3,5mm and 4,5mm for 3,5mm Implants 4,0mm and 5,0mm for 4,0mm Implants 5,0mm and 6,0mm for 5,0mm Implants
Use:	single use	singel use
Biocompatibility:	Biocompatibiliy was tested to ISO 7405	
Sterility:	Devices are not sterilized	Devices are not sterilized
Material:	titanium coated with ZircoSeal	titanium
Summary:	The Clinical House Europe healing abutment are similar as the pridicate device and made for the same indication.	
Conclusion:	The PerioType X-Pert Healing abutment is equivalent to the predicate device because they are made from the same material and they have got the same function. The only differences is that the device is coated with Zirconiumnitrid.	

Clinical House Europe GmbH
Schweiz
Fax +41 44 22010-69

K123386

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 26, 2013

Clinical House Europe GmbH
C/O Dr. Judith Weissinger
Weissinger Solutions, Inc.
9360 West Flamingo Road, Suite #110-553
LAS VEGAS NV 89147

Re: K123386
Trade/Device Name: PerioType X-Pert
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: March 26, 2013
Received: March 27, 2013

Dear Dr. Weissinger:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Digitally signed by Mary S. Runner -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Mary S. Runner -S, 0.9.2342.19200300.100.1.1=13000879
Date: 2013.04.26 08:59:36 -04'00'

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K123386

4 Indications for Use Statement

Indications for Use

510(k) Number (if known): K123386

Device Name: PerioType X-Pert

PerioType X-Pert Implants are threaded, root-form dental implants intended for use in the upper and lower jaw to support prosthetic devices, such as artificial teeth, in order to restore aesthetics and chewing function to partially or fully edentulous patients. PerioType X-Pert Dental Implant Systems are indicated for delayed loading.

The PerioType X-Pert Abutments are straight and angled dental implant Abutments to be used in conjunction with the PerioType X-Pert dental implant fixture to aid in prosthetic rehabilitation.

Prescription Use _X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page_1_of_1_

Susan Runner, DDS, MA

Digitally signed by Mary S. Runner -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Mary S. Runner -S, 0.9.2342.19200300.100.1.1=1300087950
Date: 2013.04.25 11:38:35 -04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K123386